IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TEVA PHARMACEUTICALS USA, INC.	:	CIVIL ACTION
	:	
v.	:	
	:	
AMGEN, INC.	:	NO. 09-5675

ORDER

AND NOW, this 19th day of November, 2010, upon consideration of Teva's motion to file amended pleadings (docket entry # 74), Amgen's response thereto (docket entry # 78), Amgen's motion for partial judgment on the pleadings, or, in the alternative, partial summary judgment of infringement (docket entry # 71), Teva's response thereto (docket entry # 80), and Amgen's corrected reply (docket entry # 85), and the Court finding that:

(a) Teva filed this patent declaratory judgment action on November 30, 2009; Teva's complaint, containing two counts, requests in Count I a declaratory judgment of invalidity of each claim of the '755 and '823 patents, and in Count II seeks a declaratory judgment of non-infringement of each claim of the '755 and '823 patents (docket entry # 1);

(b) On January 15, 2010, Amgen answered and counterclaimed (docket entry # 7); Amgen's single counterclaim is a claim for a declaratory judgment of infringement;

(c) On May 4, 2010, Teva filed an amended answer that admitted to infringing Amgen's patent claims if they are found valid and enforceable (docket entry # 48), and filed an amended complaint that dropped Count II, the request for a declaratory judgment of non-infringement (docket entry # 49);

(d) On May 18, 2010, Amgen filed an answer to Teva's amended complaint without amending its counterclaim (docket entry # 50);

(e) Teva now moves for leave again to amend its amended complaint and its amended answer, and Amgen moves for partial summary judgment on the pleadings, or, in the alternative, partial summary judgment of infringement;

(f) We will first address Teva's motion to amend its pleadings;

(g) We construed the meaning of "pluripotent" in our September 10, 2010 Order, and on September 29, 2010 Teva sought to amend its amended complaint to reassert Count II as a request for declaratory judgment of non-infringement of each claim of the '755 and '823 patents because Teva's Filgrastim product is not pluripotent, Teva's Mot for leave to File Amended Pleadings, Ex. A;

(h) Our April 1, 2010 Scheduling Order allowed the parties to file definitive amended pleadings by July 9, 2010;[1]

(i) Where a party seeks to amend its pleadings after a deadline set by court order, the decision whether to allow the amendment is controlled by Fed. R. Civ. P. 16(b);

(j) Under Rule 16(b), the party seeking the amendment is effectively asking the Court not only for leave to amend its pleadings, but also the scheduling order, Price v. Trans Union, LLC, No. 09-1332, 2010 WL 3310241, at *2 (E.D. Pa. Aug. 17, 2010), and because the party's request now implicates the effective administration of justice, the party must show "good cause" in order to procure the court's consent, id.;

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[1] Teva argues that this Order left open the possibility of future amended pleadings, but we disagree. When we ordered the parties to file definitive amended pleadings by July 9, 2010, we intended for the parties to do exactly that. Certainly, if there was any confusion on that score, our September 28, 2010 Order setting the deadline for the parties to complete fact discovery, exchange initial expert reports, and file dispositive motions -- without mentioning a new deadline for filing amended pleadings -- should have made it clear that no further amendments would be invited. Teva filed its motion to amend its complaint and answer one day after we issued our second scheduling order. Teva also argues that allowing it to amend its pleadings will not disturb our scheduling orders other than to extend the time to amend the pleadings. Because Teva fails to show good cause, we need not address this argument.

(k) Under Fed. R. Civ. P. 15(a), after a responsive pleading has been filed, a party may amend its pleading "only with the opposing party's written consent or the court's leave," and "[t]he court should freely give leave when justice so requires";

(l) Rule 15(a)(2) places the burden to make such a showing on the party opposing the amendment, Hildebrand v. Dentsply Int'l, Inc., 264 F.R.D. 192, 197 (E.D. Pa. 2010), and the touchstone of the rule is a showing of a prejudice to the party opposing the amendment, Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing of the V.I., Inc., 663 F.2d 419, 425 (3d Cir. 1981);

(m) The decision to grant or deny leave to amend lies within our discretion, and factors we may consider include "undue delay, bad faith, dilatory motive, prejudice, and futility," In re Burlington Coat Factory Secs. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997) (internal citations omitted);

(n) While our Court of Appeals has not explicitly addressed how to reconcile the differences in the standards between Rules 15(a) and 16(b) ("prejudice" and "good cause"),[2] other Courts in this Circuit have held that "once the pretrial

[2] That Court acknowledged this year that it has not yet addressed the tension. Race Tires America, Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 84 (3d Cir. 2010).

scheduling order's deadline for filing motions to amend the pleadings has passed, a party must, under Rule 16(b), demonstrate 'good cause' for its failure to comply with the scheduling order before the trial court can consider, under Rule 15(a), the party's motion to amend its pleading," Chancellor v. Pottsgrove Sch. Dist., 501 F. Supp. 2d 695, 701 (E.D. Pa. 2007) (Robreno, J.) (citing seven circuit court opinions applying the "good cause" standard to a motion for leave to amend the pleadings after a scheduling order deadline had passed); see also Componentone, LLC, v. Componentart, Inc., No. 05-1122, 2007 WL 2580635, at *2 (W.D. Pa. Aug. 16, 2007)(same);

(o) Amgen argues that we should not grant Teva leave to amend its complaint because Teva has not shown good cause, and even if Teva can show good cause, (1) Teva's proposed amending pleading of non-infringement is futile, and (2) Teva has unduly delayed by two months the filing of this motion to amend, and thereby has acted in bad faith;

(p) "Good cause" under Rule 16(b) focuses on the diligence of the party seeking the modification of the scheduling order, Chancellor, 501 F. Supp. 2d at 701; thus, if the party was not diligent, there is no "good cause" for modifying the scheduling order and allowing the party to file a motion to amend

its pleading, id. (citing Johnson v. Mammoth Recreations, Inc., 975 F.2d 604, 609 (9th Cir. 1992) ("If [a] party was not diligent, the inquiry should end"));

(q) "A party is presumptively not diligent if, at the commencement of the lawsuit, the party knows or is in possession of the information that is the basis for that party's later motion to amend," id. at 702;[3] without diligence, there is no "good cause," id.;

(r) This presumption may be rebutted by a clear and cognizable explanation why the proposed amendment was not included in the original pleading (or, in this case -- because it was included in the original pleading and then was withdrawn in the May 4, 2010 amended complaint -- why it was included and then withdrawn and then reasserted), id.;

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[3] In support of this principle, the Chancellor court cites S & W Enterprises v. SouthTrust Bank of Alabama, NA, 315 F.3d 533, 536 (5th Cir. 2003) ("[T]he same facts were known to [the plaintiff] from the time of its original complaint to the time it moved for leave to amend"); Parker v. Columbia Pictures Indus., 204 F.3d 326, 341 (2d Cir. 2000) (affirming the district court's denial of plaintiff's motion to amend for lack of "good cause" because the plaintiff possessed all the information he needed to support a breach of contract claim before he filed suit, "and nothing he learned in discovery or otherwise altered that fact"); Sosa v. Airprint Systems, Inc., 133 F.3d 1417, 1419 (11th Cir. 1998) ("[T]he information supporting the proposed amendment to the complaint was available to [the plaintiff] even before she filed suit.").

(s) Teva claims that when it filed its May 4, 2010 amended complaint it was not aware of the basis for its present non-infringement contention with respect to the claim term "pluripotent," and that it had to wait for us to construe that term to assert this non-infringement claim, Teva's Mem. of Law in Supp. of its Mot. for Leave to File Amended Pleadings at 5 n.2;

(t) The question we must now answer is whether the Court's September 10, 2010 Memorandum construing the claim terms qualifies as new information that provides "good cause" for us to amend the scheduling order and allow Teva to file an amended complaint;[4]

(u) Few courts have addressed this issue, but those that have addressed it have not permitted amendment based solely upon the Court's constructions of claim terms, see Mass Engineered Design, Inc. v. Ergotron, Inc., 250 F.R.D. 284, 286 (E.D. Tex. 2008) (holding that allowing a "wait and see" approach would "encourage future accused infringers to propose narrow

[4] Other than our construction of "pluripotent," Teva had all of the relevant facts prior to the July 9, 2010 deadline for filing amended pleadings. Teva's Mem. of Law in Supp. of its Mot. to File Amended Pleadings at 16 ("Teva did not seek to amend its pleadings earlier because it did not have the basis for a contention that it will not infringe all of the asserted claims until the Court entered its construction of the claim term 'pluripotent'.").

constructions focused on non-infringement while sidelining potential invalidity defenses until the Court issues its claim construction opinion" and that such "gamesmanship" should not be tolerated); Edizone, LC v. Cloud Nine, LLC, 505 F. Supp. 2d 1226, 1231 (D. Utah 2007) (finding that plaintiff's primary basis for its Rule 16 motion appeared to be the Court's claim construction memorandum, and that this was insufficient to show good cause); Atmel Corp. v. Info. Storage Devices, Inc., No. C 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998) ("Markman rulings do not constitute 'discovery of new information'");

(v) We find that Teva's argument that it needed to wait until after we had construed the claim terms does not qualify as "diligence," and that therefore Teva has not shown "good cause" for again amending its complaint or its answer;

(w) Thus, because Teva's arguments do not persuade us that it has good cause to amend its complaint after the scheduling deadline pursuant to Rule 16, we need not address Amgen's arguments that Teva also did not comply with Rule 15 and will deny Teva's motion to amend its amended complaint and answer;

(x) We next address Amgen's motion for partial summary judgment on the issue of infringement; Amgen claims that Neutroval meets each and every limitation of the first claim of the '755

patent and the second claim of the '823 patent and therefore infringes those patents;

(y) Summary judgment is appropriate if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law, Fed. R. Civ. P. 56(c); the Court must view the evidence, and make all reasonable inferences from the evidence, in the light most favorable to the nonmoving party, Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986); whenever a factual issue arises which cannot be resolved without a credibility determination, the Court must credit the non-moving party's evidence over that presented by the moving party, id. at 255; in contrast to Rule 12(c), we may consider matters outside the pleadings on summary judgment;

(z) Teva does not disagree with any of Amgen's arguments except the contention that Neutroval is pluripotent;

(aa) In our September 10, 2010 Memorandum and Order construing the claim terms, we held that "pluripotent" means "capable of generating numerous cell types," and that Amgen understood its G-CSF polypeptide to be pluripotent at the time of the patent's filing, Teva Pharmaceuticals USA, Inc. v. Amgen, Inc., No. 09-5675, slip op. at 6 (E.D. Pa. Sept. 10, 2010);

(bb) Amgen now contends that Teva's G-CSF polypeptide is pluripotent because although the "predominant effect of G-CSF with respect to terminally differentiated white blood cells is to generate neutrophil cells, neutrophils are not the only cell type that G-CSF generates," Amgen's Mot. for Part. Sum. J. ("Amgen Part MSJ") at 21; Amgen argues that "Teva's G-CSF stimulates the proliferation and differentiation of numerous cell types along the granulocyte lineage ranging from early progenitor cell types to terminally differentiated mature cell types," id.;

(cc) Amgen also argues that, at higher doses, Neutroval can also generate increases in eosinophilic granulocyte cells and basophilic granulocyte cells, id. at 22; Amgen Part MSJ, Tweardy Decl. at ¶¶ 18-24, and that this is a result of the human G-CSF "act[ing] on the earliest progenitor cells within the granulocyte lineage," Tweardy Decl. at ¶ 23; Amgen points to a Teva report that claims that "[t]reatment-related hematological findings were similar at Weeks 4, 12 and 26, comprising dose-related increased in neutrophil count (accompanied by increased basophil and/or eosinophil counts at higher doses) in treated animals...," Amgen Part MSJ, Ex. 28 at TEVA-BLA-00053111;

(dd) Amgen cited Teva's arguments during the Markman hearing in support of its contention that Neutroval is

pluripotent, Amgen Reply at 6, but Amgen itself argued in its brief for the Markman hearing that hpG-CSF is a polypeptide that can only "enhance" granulocyte production and cannot "generate" cells at all, Amgen's Resp. to Teva's Opening Claim Constr. Br. at 10, Aug. 2, 2010 (docket entry # 65);

(ee) Teva responds that although scientists at Sloan-Kettering originally believed that the factor that proved to be human G-CSF was pluripotent -- i.e., capable of generating many kinds of [mature] cell types -- they later determined that it was only capable of generating mature neutrophils, Teva's Resp. to Amgen's Part MSJ at 23;

(ff) Teva claims, through its expert, Dr. Mark D. Minden, that the slight increase in basophil and/or eosinophil counts at higher doses is not due to "generation" but rather to "mobilization," a pharmacological activity that is distinct from the generation of cell types, Teva Resp. to Amgen's Part MSJ, Minden Decl. at ¶ 42; Teva cites many scientific articles in support of the contention that G-CSF is no longer considered to be pluripotent and that any increase in eosinophils and basophils is due to mobilization and not generation, Minden Decl. at ¶ 41;

(gg) Amgen's expert, Dr. Tweardy, states, "it is my medical and scientific opinion, and the general scientific

consensus within the published scientific literature, that human G-CSF acts on the earliest progenitor cells within the granulocyte lineage, including PHSC cells. . . generating, among other things, eosinophils and basophils," Tweardy Decl. at ¶ 23; but Tweardy and Amgen cite only a single article that appears to support Teva's position regarding mobilization as opposed to generation, Tweardy Decl. at ¶ 16;

(hh) Thus, there is a material question of fact with regard to whether Teva's Neutroval generates mature cells in multiple lineages or just generates cells in the neutrophil lineage, and we must determine whether there is a genuine issue of fact with regard to the meaning of "cell types" as it is used in our construction of "pluripotent";

(ii) Amgen claims that in this context "cell types" can mean "cells within the granulocyte lineage (a single cell lineage)," while Teva claims that it means "different kinds of mature cells, i.e., the final stage of cells in different cell lineages (multiple cell lineages)";

(jj) It appears to be undisputed that murine IL-3[5] was considered to be pluripotent at the time of the filing of the patent, Amgen Reply, Ex. 9 at 36:8-20, Teva Resp. to Part. MSJ, Minden Decl. at ¶ 10; in the case of murine IL-3, it was considered to be pluripotent because "it had activity on multiple cell lineages," Amgen Reply, Ex. 9 at 36:20, Teva Resp. to Part. MSJ, Minden Decl. at ¶ 15; in addition, in Amgen's Neupogen Monograph Amgen defines "pluripotent" as denoting "the ability to produce daughter cells of different lineages," Teva's Resp. To Part. MSJ, Ex. 5 at AMT 00152578 n.6 (emphasis added);

(kk) Teva has shown that there is a genuine issue of fact as to whether its product is pluripotent because it does not generate cells along multiple cell lineages and because "pluripotent" only connotes the generation of cells along multiple cell lineages;

(ll) Thus, viewing the evidence in the light most favorable to the nonmoving party, we find that a genuine issue of fact exists with regard to whether Teva's human G-CSF is

[5] A factor able to stimulate the differentiation of hematopoietic stem cells and early progenitor cells into multiple blood cell lineages in mice. Amgen Reply, Ex. 9 at 36:8-20.

pluripotent and, therefore, whether Neutroval infringes on either claim 1 of the '755 patent or claim 2 of the '823 patent;

(mm) Because we find that there is a genuine issue of fact with regard to whether Teva's human G-CSF is pluripotent, we need not address Amgen's inducement argument;

(nn) Thus, we will deny Amgen's partial motion for summary judgment;

(oo) Because we have found a genuine issue of material fact with regard to Amgen's claim of infringement, it is premature to address Amgen's motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c);

(pp) But even if we had not found a genuine issue of material fact, it would not have been appropriate to consider Amgen's Rule 12(c) motion at this juncture for the following reasons;

(qq) The standard that a court applies to a motion for judgment on the pleadings pursuant to Rule 12(c) is the same standard that a court applies in deciding a motion to dismiss pursuant to Rule 12(b)(6), Haynes v. Metropolitan Life Ins. Co., 94 Fed. App'x 956, 958 (3d Cir. 2004); a motion for judgment on the pleadings is appropriate where there is no genuine issue of material fact and the moving party is entitled to judgment as a

matter of law, Rosenau v. Unifund Corp., 539 F.3d 218, 221 (3d Cir. 2008); we must view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party, Jablonski v. Pan Am. World Airways, Inc., 863 F.2d 289, 290-91 (3d Cir. 1988); a plaintiff may not win judgment on the pleadings when a defendant's pleadings raise issues of fact that would defeat recovery if proven, AMCO Ins. Co. v. Swagat Group, LLC, No. 07-3330, 2009 WL 331539, at *3 (C.D. Ill. Feb. 10, 2009).

(rr) Amgen argues that when Teva admitted in its answer that its product "will infringe certain claims of the '823 and the '755 patents, to the extent those claims are found valid and enforceable," this constituted both an admission of infringement and a failure to deny infringement under Fed. R. Civ. P. 8(b)(6), Amgen Part MSJ at 13;

(ss) An admission in a pleading cannot be a judicial admission if it is, in part, dependant upon a legal consideration, MacDonald v. General Motors Corp., 110 F.3d 337, 341 (6th Cir. 1997); Glick v. White Motor Co., 458 F.2d 1287, 1291 (3d Cir. 1972) ("The scope of judicial admissions is restricted to matters of fact which otherwise would require evidentiary proof"); in addition, to be a binding judicial admission, it must be

unequivocal, Philadelphia Reinsurance Corp. v. Emp'rs Ins. of Wausau, 61 Fed. App'x 816, 819 (3d Cir. 2003);

(tt) Amgen supports its Rule 12(c) motion by citing Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573 (Fed. Cir. 1983), in which the Federal Circuit found that a party's failure to deny the alleged infringement in its pleadings amounted to an admission of infringement;

(uu) But that case is inapposite; in Smith Int'l, the validity of the patent had already been confirmed by the Ninth Circuit, and therefore the admission of infringement, on remand, could be found to be a judicial admission of fact; the court held that "[t]he Ninth Circuit Court's decision removed any question about the validity and enforceability of the patents. Therefore, we have before us a clear admission," id. at 1580;

(vv) Here, unlike in Smith Int'l, there is still a mixed question of law and fact in the statement that Teva's product "will infringe certain claims of the '823 and the '755 patents, to the extent those claims are found valid and enforceable," Teva's Amended Answer to Amgen's Counterclaim (docket entry # 48) at ¶ 29;

(ww) We find that Teva's admission of infringement is conditioned upon the validity of the patent claims and thus we

could not, at this point, find that it is an unequivocal admission of infringement;

(xx) In its Reply, Amgen argues that Teva's failure to deny its allegation of infringement in responsive pleading results in an admission of that allegation;

(yy) While it is true that Teva has failed to deny infringement outright, any claim of infringement depends upon whether the patent is valid; Teva notes that requests for admissions concerning infringement call for a legal conclusion and do not require a response, Teva's Resp. to Amgen's Part MSJ at 5 n.2;

(zz) We agree, and accept the reasoning set forth in Tulip Computers Intern., B.V. v. Dell Computer Corp., 210 F.R.D. 100, 108 (D. Del. 2002)(holding that determining whether a patent is valid calls for a legal conclusion and thus is not allowed under Fed. R. Civ. P. 36); thus, this argument would have failed as well;

(aaa) Because we have found a genuine issue of material fact with regard to whether Teva's product is pluripotent, we will deny Amgen's motion for summary judgment regarding infringement;

It is hereby ORDERED that:

1. Teva's motion to file amended pleadings (docket entry # 74) is DENIED; and

2. Amgen's motion for partial judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c) or, in the alternative, for partial summary judgment of infringement (docket entry # 71) is DENIED.

BY THE COURT:

__\s\Stewart Dalzell